REMARKS

Applicants respectfully request reconsideration of this application in view of the following remarks.

I. Status of the Claims

Claims 1, 44, 45, 50, 51, 64-66, and 71-72 and withdrawn claims 56-62 and 77-83 are amended to recite specific embodiments. Claims 46-48 and 67-69 are canceled. These amendments are made without prejudice or disclaimer and Applicants reserve the right to pursue any canceled subject matter in one or more continuing applications with the same rights of priority as the instant application.

The amendments to clarify that the charged antigen is a "positively" charged antigen are supported throughout the specification as filed, including at page 11, lines 8-10, and page 13, lines 7-11. The amendments to recite specific embodiments of the antigen are supported throughout the specification as filed, including at pages 12-13 and 19-21. Thus, no new matter is added.

Upon entry of the amendments, claims 1, 44-45, 49-66, and 70-99 will be pending. Claims 1, 44-45, 49-55, 63-66, 70-76 and 84-85 are under examination, while claims 56-62, 77-83 and 86-99 are withdrawn from consideration. These claims are retained as subject to rejoinder upon allowance of the elected subject matter.

III. Novelty

A. Rejections over Simmonds

Claims 1, 44, 46-55, 64-76 and 85 were rejected as allegedly anticipated by Simmonds A (WO 94/25602; §102(b)); Simmonds B (U.S. Patent 6,881,821; § 102(e)); or Simmonds C (U.S. Patent 7,198,892; §102(e)), in light of teachings by Sjolander (1998). Applicants respectfully traverse these rejections.

The rejected claims are directed to "an immunogenic complex comprising a negatively charged organic complex and a positivley charged antigen, which organic complex and antigen are electrostatically associated," and wherein the charged antigen comprises one

or more polypeptides from a specified region of HCV, and to compositions comprising such a complex. This subject matter is not taught or suggested by the cited references.

As explained previously, Simmonds A-C are directed to peptides that are described as being type-specific to HCV-4, HCV-5, and HCV-6. Thus, the focus of Simmonds A-C is the description of these peptides *per se*, not their formulation into novel immunogenic complexes, as claimed. The only portion of Simmonds with any relevance to the present invention appears to be the bald statement that the disclosed peptides "may optionally be ***attached*** to a particulate structure, such as liposomes or ISCOMS" (emphasis added). This teaching, however, does not anticipate the present invention, because it only suggests "attaching" the peptides to an ISCOM, not preparing an ***electrostatically associated*** complex, as recited in the instant claims.

The Office Action alleges that Simmonds inherently anticipates the "electrostatically associated" aspect of the claimed complex, but that is simply not true. Assuming for the sake of argument only that Simmonds teaches the attachment of a positively charged antigen to a negatively charged ISCOM, such an attachment need not be electrostatic, but could involve, for example, a covalent bond (as illustrated in the Lovgren and Barr references discussed in Applicants' previous response), or some other means of attachment. Inherent anticipation is not met by mere possibilities or probabilities. *Trintec Indus., Inc. v. Top-U.S.A. Corp.*, 295 F.3d 1292, 1295 (Fed. Cir. 2002); *Scaltech, Inc. v. Retec/Tetra, LLC.*, 178 F.3d 1378, 1384 (Fed. Cir. 1999). Because Simmonds' antigens could be "attached" to ISCOMs in a manner that does not involve electrostatic association, the record does not support the inherent anticipation theory.

More importantly, Simmonds does not in fact teach the attachment of a ***positively*** charged antigen to a negatively charged ISCOM. For example, a review of the peptides reported in Example 3 of Simmonds B reveals that each peptide is ***negatively*** charged. This is in direct contrast to the positively charged antigens recited in the instant claims. Indeed, the negatively charged peptides described in Simmonds could not be "electrostatically associated" with a negatively charged organic complex, as recited in the instant claims. Because Simmonds does not teach or suggest the selection of positively charged HCV

peptides for electrostatic attachment to a negatively charged organic complex, it simply cannot anticipate the present invention.

For at least these reasons, Simmonds A-C fail to teach a complex or composition meeting every limitation of the rejected claims. Thus, the §102 rejections are improper and should be withdrawn.

A. Rejections over Garcon

The Office Action newly rejects claims 1, 44, 46-51, 55, 64-65, 67-72 and 75 as allegedly anticipated by Garcon (WO 96/33739). Applicants respectfully traverse this rejection.

Garcon was cited for teaching an immunogenic composition comprising an antigen, saponin, cholesterol and MPL, where the components allegedly are constituted in an ISCOM. The teachings of Garcon, however, do not anticipate the claimed invention.

Garcon is broadly directed to vaccine compositions comprising an antigen, saponin, a sterol and, in some embodiments, MPL. Most of the disclosure and examples of Garcon relates to its "preferred compositions" which comprise liposomes. Page 2 states that the invention includes "compositions where the sterol/immunologically active saponin fraction forms an ISCOM structure," but that is the only teaching Applicants could find in Garcon that relates to ISCOMs. Notably, there is no express disclosure of how such an ISCOM would be formulated with the antigen. Pages 4-5 of Garcon cite references that describe methodoliges that can be used in making its vaccines. Page 5 cites U.S. Patent 4,235,877 for encapsulation with liposomes, and cites U.S. Patent 4,372,945 and U.S. Patent 4,474,757 for "[c]onjugation of proteins to macromolecules." Notably, the '945 and '757 patents disclose covalent conjugation methodoligies. (Copies of these patents are attached hereto for the Examiner's convenience).

Thus, as with the Simmonds references, there is no teaching or suggestion in Garcon to form an electrostatically associated immunogenic complex, as recited in the instant claims. Moreover, as with the Simmonds references, there is no teaching or suggestion in Garcon to select positively charged antigens when practicing its ISCOM embodiment and, hence, no anticipation of the recited immunogenic complex that comprises a negatively charged organic complex and a positively charged antigen.

For at least these reasons, Garcon fails to teach a complex or composition meeting every limitation of the rejected claims. Thus, the §102 rejection is improper and should be withdrawn.

IV. Non-Obviousness

Claims 1, 44-55, 63-76 and 84-85 were rejected under 35 U.S.C. § 103(a) as allegedly obvious over Simmons A-C in combination with Cerny (1995). Applicant respectfully traverses these rejections.

The inability of Simmonds A-C to teach or suggest the claimed invention is shown above. While Cerny is cited for teaching HCV T-cell epitopes, combining Simmonds A-C with Cerny does not resolve Simmond's inability to teach or suggest the claimed immunogenic complexes. In particular, combining Simmonds with Cerny still leaves the skilled artisan with no guidance to form "an immunogenic complex comprising a negatively charged organic complex and a positively charged antigen," wherein the "organic complex and antigen are electrostatically associated." Because no cited combination of references teaches or suggests such an immunogenic complex, the §103 rejections are improper and should be withdrawn.

IV. Concluding Remarks

Applicants believe that this application is in condition for allowance, and an early notice to that effect is earnestly solicited.

Should there be any questions regarding this submission, or should any issue remain, the Examiner is invited to contact the undersigned attorney by telephone in order to advance prosecution.

The Commissioner is hereby authorized to charge any additional fees that may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check or credit card payment form being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extensions under 37 C.F.R. §1.136 and authorize payment of any extension fees to Deposit Account No. 19-0741.

Respectfully submitted,

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